



114TH CONGRESS  
1ST SESSION

**S.** \_\_\_\_\_

To provide for the creation of a safe harbor for defendants in medical malpractice actions who demonstrate adherence to clinical practice guidelines.

IN THE SENATE OF THE UNITED STATES

Mr. BARRASSO introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

*for himself  
and Mrs. Capito*

## A BILL

To provide for the creation of a safe harbor for defendants in medical malpractice actions who demonstrate adherence to clinical practice guidelines.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

### 3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Saving Lives, Saving  
5 Costs Act".

### 6 **SEC. 2. REQUIREMENTS FOR SELECTION OF CLINICAL** 7 **PRACTICE GUIDELINES.**

8 (a) SELECTION.—Not later than 6 months after the  
9 date of enactment of this Act, eligible professional organi-  
10 zations that have established, published, maintained, and

1 updated on a regular basis, clinical practice guidelines, in-  
2 cluding when applicable, appropriate use criteria, that in-  
3 corporate best practices, may submit such guidelines to  
4 the Secretary. Not later than 6 months after the last day  
5 for submitting such guidelines, the Secretary shall select  
6 and designate one or more eligible professional organiza-  
7 tions to provide and maintain such clinical practice guide-  
8 lines on behalf of the Secretary. Not later than 6 months  
9 after designating each such eligible professional organiza-  
10 tion, the Secretary shall enter into an agreement with each  
11 such eligible professional organization for maintenance,  
12 publication, and updating of such clinical practice guide-  
13 lines.

14 (b) MAINTENANCE.—

15 (1) PERIODIC REVIEW.—Not later than 5 years  
16 the Secretary enters into an agreement with each el-  
17 igible professional organization under subsection (a),  
18 and every 5 years thereafter, the Secretary shall re-  
19 view the clinical practice guidelines of such organiza-  
20 tion and shall, as necessary, enter into agreements  
21 with additional eligible professional organizations, as  
22 appropriate, in accordance with subsection (a).

23 (2) UPDATE BY ELIGIBLE PROFESSIONAL ORGA-  
24 NIZATION.—An eligible professional organization  
25 that collaborated in the establishment of a clinical

1 practice guidelines may submit amendments to that  
2 clinical practice guideline at any time to the Sec-  
3 retary for review by the Secretary.

4 (3) NOTIFICATION REQUIRED FOR CERTAIN UP-  
5 DATES.—An amendment under paragraph (2) may  
6 not add, materially change, or remove a guideline  
7 from a set of guidelines, unless notification of such  
8 update is made available to applicable eligible profes-  
9 sionals.

10 **SEC. 3. DEVELOPMENT.**

11 (a) GUIDELINE STANDARDS.—The Secretary shall  
12 ensure that, to the extent practicable, the development of  
13 clinical practice guidelines are guided by the Standards  
14 for Developing Trustworthy Clinical Practice Guidelines of  
15 the Institute of Medicine and—

16 (1) are developed through a transparent process  
17 that minimizes conflicts of interest;

18 (2) are developed by a knowledgeable, multi-  
19 disciplinary panel of experts and representatives  
20 from key affected groups;

21 (3) take into consideration important patient  
22 subgroups and patient preferences, as appropriate;

23 (4) are based on a systematic review of the ex-  
24 isting evidence;

1           (5) provide a clear explanation of the relation-  
2           ship between care options and health outcomes;

3           (6) provide ratings of both the quality of evi-  
4           dence and strength of recommendation;

5           (7) are reconsidered and revised when new evi-  
6           dence emerges; and

7           (8) clearly identify any exceptions to the appli-  
8           cation of the clinical practice guideline.

9           (b) REQUIRED DISCLOSURES FROM ELIGIBLE PRO-  
10          FESSIONAL ORGANIZATIONS.—Any person who is affili-  
11          ated with an eligible professional organization and who di-  
12          rectly participated in the creation of a clinical practice  
13          guideline shall disclose any conflicts of interest pertaining  
14          to the development of the clinical practice guideline, in-  
15          cluding any conflict of interest pertaining to any instru-  
16          ment, medicine, drug, or any other substance, device, or  
17          means included in the clinical practice guideline. Disclo-  
18          sures to the Secretary by eligible professional organiza-  
19          tions shall be made promptly, upon submission of the  
20          guidelines, and during every review of the guidelines. Dis-  
21          closures shall include the following:

22               (1) Scientific methodology and evidence that  
23               supports clinical practice guidelines.

24               (2) Outside collaborators.

25               (3) Endorsements.

1 **SEC. 4. NO LIABILITY FOR GUIDELINE PRODUCERS.**

2 Neither an eligible professional organization nor the  
3 participants in its guideline development and approval  
4 process, may be held liable for any injury alleged to be  
5 caused by adhering to a clinical practice guideline to which  
6 they contributed.

7 **SEC. 5. INTERNET PUBLICATION OF GUIDELINES.**

8 The Secretary shall publish on the Internet through  
9 the National Guideline Clearinghouse or other appropriate  
10 sites or sources, all clinical practice guidelines, including  
11 all data and methodology used in the development and se-  
12 lection of the guidelines in compliance with data disclosure  
13 standards in the Health Insurance Portability and Ac-  
14 countability Act of 1996 (Public Law 104–191).

15 **SEC. 6. STATE FLEXIBILITY AND PROTECTION OF STATES'**  
16 **RIGHTS.**

17 (a) **LIMITATION.**—This Act shall not preempt or su-  
18 persede any State or Federal law that—

19 (1) imposes procedural or substantive protec-  
20 tions for health care providers and health care orga-  
21 nizations from liability, loss, or damages greater  
22 than such protections provided by this title; or

23 (2) creates a cause of action related to the pro-  
24 vision of health care goods or services.

25 (b) **STATE FLEXIBILITY.**—No provision of this Act  
26 shall be construed to preempt any defense available to a

1 party in a health care liability action under any other pro-  
2 vision of State or Federal law.

3 **SEC. 7. FEDERAL CAUSE OF ACTION.**

4 (a) IN GENERAL.—Chapter 85 of title 28, United  
5 States Code, is amended by adding at the end the fol-  
6 lowing:

7 **“§ 1370. Health care liability claims**

8 “(a) DEFINITIONS.—In this section, the terms ‘appli-  
9 cable eligible professional’, ‘health care goods or services’,  
10 ‘health care liability action’, ‘health care liability claim’,  
11 ‘health care organization’, and ‘health care provider’ have  
12 the meaning given such terms in section 10 of the Saving  
13 Lives, Saving Costs Act.

14 “(b) JURISDICTION OF CLAIMS.—The district courts  
15 shall have original jurisdiction of a health care liability ac-  
16 tion against an applicable eligible professional, health care  
17 provider, or health care organization.

18 “(c) SUBSTANTIVE LAW.—The substantive law for  
19 decision in a health care liability action brought under  
20 subsection (b) shall be derived from the law, including  
21 choice of law principles, of the State in which the provision  
22 of, use of, or payment for (or the failure to provide, use,  
23 or pay for) health care goods or services giving rise to  
24 the health care liability claim occurred unless such law is  
25 inconsistent with or preempted by Federal law.”.

1 (b) TECHNICAL AND CONFORMING AMENDMENT.—

2 The table of sections for chapter 85 of title 28, United  
3 States Code, is amended by adding at the end the fol-  
4 lowing:

“1370. Health care liability claims.”.

5 **SEC. 8. RIGHT OF REMOVAL.**

6 Section 1441 of title 28, United States Code, is  
7 amended by adding at the end the following:

8 “(g) CERTAIN ACTIONS AGAINST MEDICAL PROFES-  
9 SIONALS.—(1) A health care liability action brought in a  
10 State court against an applicable eligible professional,  
11 health care provider, or health care organization may be  
12 removed by any defendant or the defendants to the district  
13 court of the United States for the district and division em-  
14 bracing the place where such action is pending.

15 “(2) In this subsection, the terms ‘applicable eligible  
16 professional’, ‘health care liability action’, ‘health care or-  
17 ganization’, and ‘health care provider’ have the meaning  
18 given such terms in section 10 of the Saving Lives, Saving  
19 Costs Act.”.

20 **SEC. 9. MANDATORY REVIEW BY INDEPENDENT MEDICAL**  
21 **PANEL.**

22 (a) IN GENERAL.—If, in any health care liability ac-  
23 tion removed to Federal court pursuant to section 1441(g)  
24 of title 28, United States Code, against an applica-  
25 ble professional, health care provider, or health care orga-

1 nization, the applicable eligible professional, health care  
2 provider, or health care organization alleges, in response  
3 to a filing of the claimant, that the applicable eligible pro-  
4 fessional, health care provider, or health care organization  
5 adhered to an applicable clinical practice guideline in the  
6 provision of health care goods or services to the claimant,  
7 then the court shall suspend further proceedings on the  
8 health care liability action prior to discovery proceedings,  
9 until the completion of a review of the action by an inde-  
10 pendent medical review panel.

11 (b) INDEPENDENT MEDICAL REVIEW PANEL.—

12 (1) COMPOSITION.—An independent medical re-  
13 view panel under this section shall be composed of  
14 3 members who are experts in the relevant field of  
15 clinical practice, appointed in accordance with para-  
16 graph (5).

17 (2) REQUIREMENTS FOR MEMBER ELIGI-  
18 BILITY.—

19 (A) IN GENERAL.—To be eligible to serve  
20 on an independent medical review panel, a  
21 member shall—

22 (i) be an experienced physician cer-  
23 tified by a board recognized by the Amer-  
24 ican Board of Medical Specialties;



1 (ii) not earlier than 2 years prior to  
2 the date of selection to the board, have  
3 been in active medical practice or devoted  
4 a substantial portion of his or her time to  
5 teaching at an accredited medical school,  
6 or have been engaged in university-based  
7 research in relation to the medical care  
8 and type of treatment at issue; and

9 (iii) be approved by his or her spe-  
10 cialty society.

11 (B) REGIONAL PREFERENCE.—When pos-  
12 sible, members should be from the region where  
13 the case in question originates to account for  
14 geographical practice variation.

15 (3) NO CIVIL LIABILITY FOR MEMBERS.—No  
16 civil action shall be brought in any court against any  
17 member for any act, failure to act, or statement or  
18 opinion made, within the scope of his or her duties  
19 as a member of the independent medical review  
20 panel.

21 (4) CONSIDERATIONS IN MAKING DETERMINA-  
22 TIONS.—The members of the independent medical  
23 review panel shall acknowledge that, under certain  
24 circumstances, it may be appropriate for a physician

1 to depart from the recommendations in clinical prac-  
2 tice guidelines in the care of individual patients.

3 (5) SELECTION OF MEMBERS.—Each member  
4 of the independent medical review panel shall be  
5 jointly selected by the parties. A member whose se-  
6 lection one party does not concur in may not serve  
7 on the panel, except that, if, not later than 30 days  
8 after a response to the health care liability action is  
9 filed, 3 members have not been selected by the par-  
10 ties, the court shall appoint any remaining members.

11 (6) COMPENSATION OF MEMBERS.—The costs  
12 of compensation to the members of the independent  
13 medical review panel shall be shared between the  
14 parties equally, unless otherwise agreed to by the  
15 parties.

16 (c) TERMS OF REVIEW.—A review by an independent  
17 medical review panel under this section shall comply with  
18 the following:

19 (1) STANDARD OF CONDUCT.—The mandatory  
20 independent medical review panel that is charged  
21 with the responsibility of making a preliminary find-  
22 ing as to liability of the defendant applicable eligible  
23 professional shall deem the prescribed clinical prac-  
24 tice guidelines as the standard of conduct, care, and  
25 skill expected of members of the medical profession

1 engaged in the defendant's field of practice under  
2 the same or similar circumstances, subject to the  
3 provisions of subsection (b)(4).

4 (2) RECORD FOR REVIEW.—The independent  
5 medical review panel shall make a preliminary find-  
6 ing based solely upon the pre-discovery evidence sub-  
7 mitted to it pursuant to Rule 26 of the Federal  
8 Rules of Civil Procedure, any medical records that  
9 would be discoverable if the lawsuit advances to  
10 trial, and the applicable prescribed clinical practice  
11 guidelines.

12 (3) LIMITATION.—The independent medical re-  
13 view panel shall not make a finding of negligence  
14 from the mere fact that a treatment or procedure  
15 was unsuccessful or failed to bring the best result,  
16 or that the patient died.

17 (4) USE AT TRIAL OF WORK PRODUCT OF RE-  
18 VIEW PANEL.—No preliminary finding by the inde-  
19 pendent medical review panel that the defendant ap-  
20 plicable eligible professional breached the standard  
21 of care as set forth under the prescribed clinical  
22 practice guidelines shall constitute negligence per se  
23 or conclusive evidence of liability, but findings, opin-  
24 ions, and conclusions of the review panel shall be ad-  
25 missible as evidence in any and all subsequent pro-

1       ceedings before the court, including for purposes of  
2       motions for summary judgment and at trial.

3       (d) RESULTS OF REVIEW.—

4           (1) IN GENERAL.—Not later than 60 days after  
5       all members of the independent medical review panel  
6       have been selected, the panel shall complete a review  
7       of the record of the liability action and shall make  
8       a finding under this subsection.

9           (2) FINDING DESCRIBED.—A finding under this  
10       subsection shall include the following:

11           (A) A determination of whether there are  
12       any applicable clinical practice guidelines to the  
13       health care liability action that substantively  
14       pertains to the injury suffered by the claimant.

15           (B) Whether the applicable eligible profes-  
16       sional has alleged adherence to any such guide-  
17       line.

18           (C) Whether the applicable eligible profes-  
19       sional adhered to any such guideline.

20           (D) Whether there is a reasonable prob-  
21       ability that—

22           (i) the applicable eligible professional  
23       violated the applicable clinical practice  
24       guideline;

- 1 (ii) that violation proximately caused  
2 the claimant's alleged injury; and  
3 (iii) the claimant suffered damages as  
4 a result of the injury.

5 (3) USE AT TRIAL.—The finding under this  
6 subsection may be received into evidence by the  
7 court. If the independent medical review panel made  
8 any finding under paragraph (2)(D) that there was  
9 no reasonable probability of the matters described in  
10 clauses (i) through (iii), the court may issue a sum-  
11 mary judgment in favor of the applicable eligible  
12 professional unless the claimant is able to show oth-  
13 erwise by clear and convincing evidence. If the panel  
14 made a finding under subparagraphs (A) through  
15 (C) of paragraph (2) that there was an applicable  
16 clinical practice guideline that the defendant adhered  
17 to, the court shall issue summary judgment in favor  
18 of the applicable eligible professional unless the  
19 claimant is able to show otherwise by clear and con-  
20 vincing evidence. Any preliminary finding that the  
21 defendant applicable eligible professional did not  
22 breach the standard of care as set forth under the  
23 prescribed medical practice guidelines or that the de-  
24 fendant applicable eligible professional's nonadher-  
25 ence to the applicable standard was neither the

1 cause in fact nor the proximate cause of the plain-  
2 tiff's injury or that the plaintiff did not incur any  
3 damages as a result shall be given deference by the  
4 court and shall entitle the defendant applicable eligi-  
5 ble professional to summary judgment unless the  
6 plaintiff is able to show by clear and convincing evi-  
7 dence that the independent medical review panel was  
8 in error and that there is a genuine issue as to a  
9 material fact in the case.

10 **SEC. 10. DEFINITIONS.**

11 In this Act:

12 (1) **APPLICABLE ELIGIBLE PROFESSIONAL.**—

13 The term “applicable eligible professional” means a  
14 physician practicing within clinical practice guide-  
15 lines submitted by an eligible professional organiza-  
16 tion and includes employees and agents of a physi-  
17 cian.

18 (2) **APPROPRIATE USE CRITERIA.**—The term

19 “appropriate use criteria” means established evi-  
20 dence-based guidelines developed or endorsed by an  
21 eligible professional organization that specify when  
22 the health benefits of a procedure or service exceed  
23 the expected health risks by a significantly wide  
24 margin.

1           (3) CLINICAL PRACTICE GUIDELINE.—The term  
2           “clinical practice guideline” means systematically de-  
3           veloped statements based on the review of clinical  
4           evidence for assisting a health care provider to de-  
5           termine the appropriate health care in specific clin-  
6           ical circumstances.

7           (4) ELIGIBLE PROFESSIONAL ORGANIZATION.—  
8           The term “eligible professional organization” means  
9           a national or State medical society or medical spe-  
10          cialty society.

11          (5) FEDERAL PAYOR.—The term “Federal  
12          payor” includes reimbursements made under the  
13          Medicare program under title XVIII of the Social  
14          Security Act or the Medicaid program under title  
15          XIX of the Social Security Act, premium tax credits  
16          under section 36B of the Internal Revenue Code of  
17          1986 or cost-sharing reductions under section 1402  
18          of the Patient Protection and Affordable Care Act,  
19          or medical screenings, treatments, or transfer serv-  
20          ices provided pursuant to section 1867 of the Social  
21          Security Act is not made by the individual or any  
22          non-Federal third party on behalf of the individual.

23          (6) HEALTH CARE GOODS OR SERVICES.—The  
24          term “health care goods or services” means any  
25          goods or services provided by a health care organiza-

1       tion, provider, or by any individual working under  
2       the supervision of a health care provider, that relates  
3       to the diagnosis, prevention, or treatment of any  
4       human disease or impairment, or the assessment or  
5       care of the health of human beings.

6           (7) HEALTH CARE LIABILITY ACTION.—The  
7       term “health care liability action” means a civil ac-  
8       tion against an applicable eligible professional, a  
9       health care provider, or a health care organization,  
10      regardless of the theory of liability on which the  
11      claim is based, or the number of plaintiffs, defend-  
12      ants, or other parties, or the number of causes of ac-  
13      tion, in which the claimant alleges a health care li-  
14      ability claim.

15          (8) HEALTH CARE LIABILITY CLAIM.—The  
16      term “health care liability claim” means a claim by  
17      any person against an applicable eligible profes-  
18      sional, a health care provider, or a health care orga-  
19      nization which is based upon the provision of, use of,  
20      or payment for (or the failure to provide, use, or pay  
21      for) health care goods or services for which at least  
22      partial payment was made by a Federal payor or  
23      which was mandated by Federal law, regardless of  
24      the theory of liability on which the claim is based.



1           (9) HEALTH CARE ORGANIZATION.—The term  
2           “health care organization” means any person or en-  
3           tity which is obligated to provide or pay for health  
4           benefits under any health plan, including any person  
5           or entity acting under a contract or arrangement  
6           with a health care organization to provide or admin-  
7           ister any health benefit.

8           (10) HEALTH CARE PROVIDER.—The term  
9           “health care provider” means any person or entity  
10          required by State or Federal laws or regulations to  
11          be licensed, registered, or certified to provide health  
12          care services, and being either so licensed, reg-  
13          istered, or certified, or exempted from such require-  
14          ment by other statute or regulation.

15          (11) SECRETARY.—The term “Secretary”  
16          means the Secretary of Health and Human Services.